



H5N1 Pre-Pandemic Influenza Vaccine Stockpile

RAC HPAI Meeting

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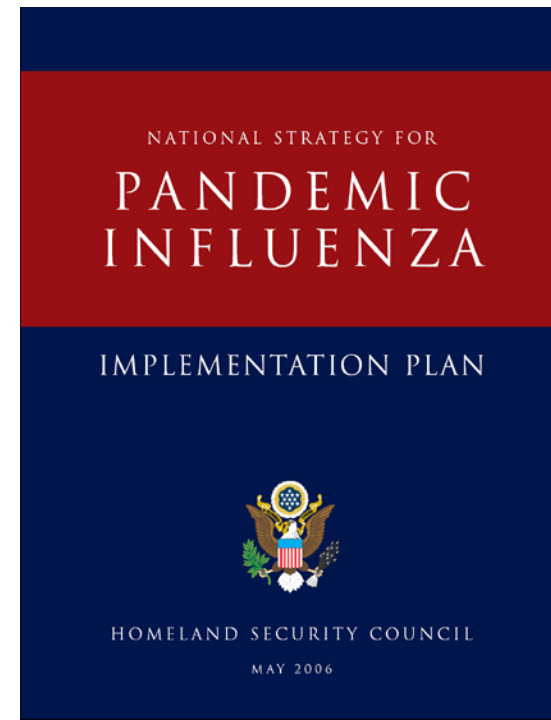
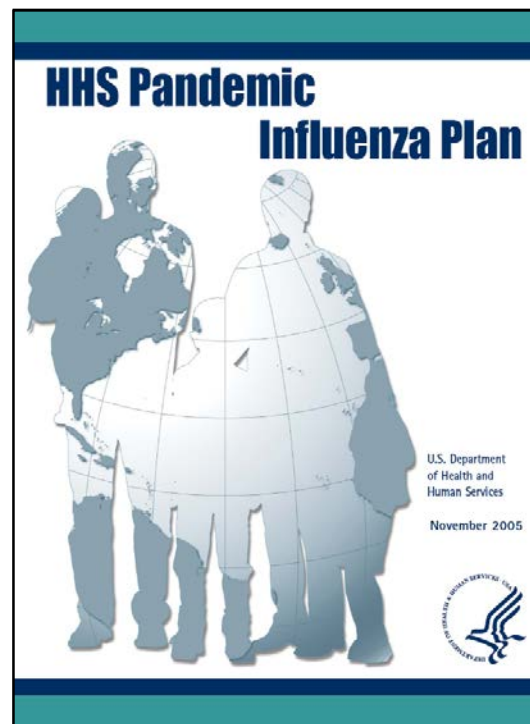
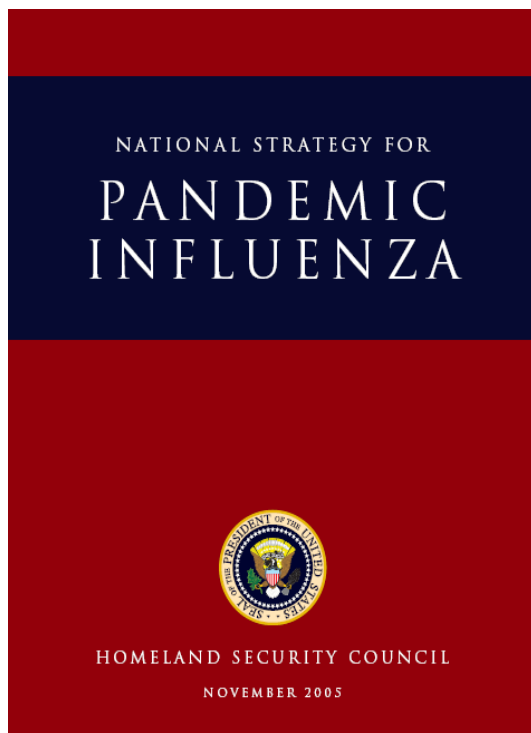
Deputy Assistant Secretary, ASPR

Dr. Armen Donabedian, BARDA

January 24, 2013



U.S. Pandemic Influenza Plans Laid the Pathway for Pandemic Vaccines





Vaccine Strategic Goals Were Specific on Expectations



- **Goal #1: Establish & maintain dynamic pre-pandemic influenza vaccine stockpiles available for 20 M persons (2 doses/person): H5N1 stockpiles**
- **Goal #2: Provide pandemic vaccine to all U.S. citizens within 6 months of a pandemic declaration: pandemic vaccine (600 M doses)**

National Strategy for Pandemic Influenza (Nov 2005) and HHS Pandemic Influenza Plan (Nov 2005)

www.pandemicflu.gov



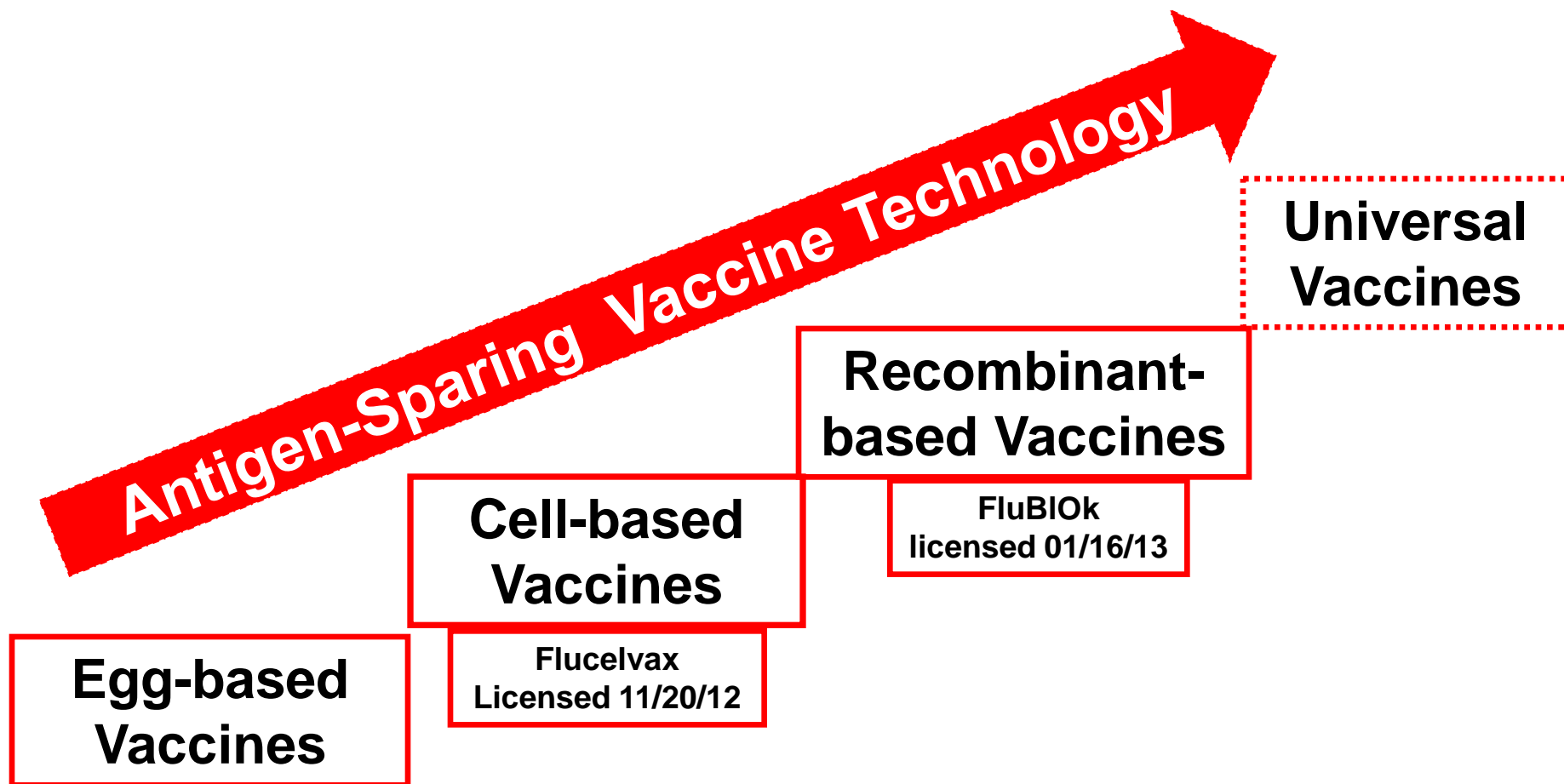
Pandemic Influenza Vaccine Implementation Goals



- **Fortify existing influenza vaccine capabilities**
- **Support development of better influenza vaccines that afford greater surge manufacturing capacity**
 - Cell-based Vaccines
 - Recombinant and Molecular Vaccines
 - Adjuvants for Dose- and Antigen-sparing
 - Universal Influenza Vaccines
- **Establish pre-pandemic influenza vaccine stockpile**
- **Expand domestic manufacturing capacity**
 - Retrofit existing facilities
 - Establish new facilities



National Pandemic Influenza Vaccine Development Strategy Is Multi-Step & Integrated Approach



“More and better vaccines sooner”



HHS Has Established H5N1 Vaccine Stockpile Available for Deployment



- **HHS/BARDA established & manages H5N1 vaccine antigen (4 strains) and adjuvant (2) stockpiles stored and routinely tested at multiple domestic vaccine manufacturing sites**
- **U.S. pan flu preparedness stockpiling goal met in 2008**
- **Stockpile needs evaluated annually using CDC'S Influenza Risk Assessment Tool (e.g., H3N2v – 2012)**
- **Potency of bulk vaccine antigen lots remains >75% after 5-8 years & bulk adjuvant lots near 100% after 4-5 years**
- **Pre-EUA packages provided by BARDA in 2012 to FDA for stockpiled vaccines with adjuvants**
- **Vaccine distribution through central distribution system managed by CDC**
- **An IND-based program with a vaccine manufacturer to provide H5N1 vaccine to at risk lab & mfg. workers**



Current U.S. H5N1 Pre-Pandemic Influenza Bulk* Vaccine Stockpiles



H5N1 Bulk Vaccine Strain (Clade)	2005	2006	2007	2008	2012	M doses @ 90 µg/dose	M doses @ 7.5 µg/dose	M doses @ 3.75 µg/dose
A/VTN/1203/04 (1)	1.99	1.20		0.54		3.73	46.8	93.6
A/Indo/05/05 (2.1.3)		5.49	2.29	0.04		7.82	93.1	186.2
A/BHG/QL/1A/05 (2.2)			4.11			4.11	49.3	98.6
A/Anhui/1/05 (2.3.4)			1.07			1.07	12.8	25.6
A/Egypt/N03072/10 (2.2.1) Cell-based					TBD			
Totals	1.99	6.69	7.47	0.89		16.73	202	404

* A small amount of vaccine and adjuvant are available filled in multi-dose vials.



Concluding Remarks



- **Safety and efficacy of H5N1 vaccines**
- **H5N1 pre-pandemic preparedness enhances biosafety**
- **BARDA supports BSL3 enhanced laboratory practices for research with highly pathogenic H5N1 influenza virus**